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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/655,911	09/05/2003	Arturo J. Angel	524522000500	7674

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MORRISON & FOERSTER LLP
755 PAGE MILL RD
PALO ALTO, CA 94304-1018

EXAMINER

CHANNAVAJJALA, LAKSHMI SARADA

ART UNIT	PAPER NUMBER
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1615

DATE MAILED: 06/03/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/655,911

Applicant(s)

ANGEL ET AL.

Examiner

Lakshmi S. Channavajjala

Art Unit

1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-24 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-24 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 2-17-04, 8-9-04; 2/22/05

- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: ____.

Art Unit: 1615

DETAILED ACTION

Receipt of IDS dated 2-22-05, 8-9-04 and 2-17-04 is acknowledged.

Claims 1-24 are pending in the instant application.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-24 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-20 of copending Application No. 10/810,185. Although the conflicting claims are not identical, they are not patentably distinct from each other because instant composition comprising capsaicin, polyethylene glycol, polyacrylate thickening agent etc., reads on the composition used in the method of treating recited in the co-pending application. Instant composition is used for the same method as that of the copending application i.e., cleansing the body surface and reducing pain. The copending application also recites the claimed solubilizer, solubility parameters, thickener, pH etc. Therefore, it would have been obvious for one of an ordinary skill in the art at the time of the instant invention to

Art Unit: 1615

prepare the composition of the copending claims as a kit, with the instructions of use and also in the form of a transdermal patch because the co-pending claims also recite the capsaicin composition in the form of a patch and the instant composition as well as the co-pending composition is used for the same purpose i.e., to reduce the pain or the irritation caused by applying topical application to a person to treat capsaicin responsive condition. Further, optimizing the amounts of the carrier, thickener etc., would have been within the scope of a skilled artisan.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

Art Unit: 1615

consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5, 856,361 to Holt in view of Wholehealthmd (data sheet).

Holt teaches a pain reliever composition and a method comprising capsaicin together with another ingredient to neutralize the discomfort caused by capsaicin application to skin. The discomfort and the pain associated with capsaicin listed by Holt include the claimed neuropathic pain etc. (abstract, paragraph between col. 1-2 and col. 5). The composition of Holt includes the second active agent that reduces the skin irritation caused by capsaicin, so as to form a solution, lotion or a patch (col. 2). Holt further teaches adding carriers and thickening agents in the composition so as to provide the required or desired consistency (col. 3). Among the second active agent, Holt teaches polyethylene glycol (PEG)(col. 5, lines 14-22 and example). While Holt does not specially teach treating first with capsaicin and then washing or neutralizing with a carrier, as claimed, Holt does teach applying two components i.e., first capsaicin and a second anesthetic agent such as polyethylene glycol. Thus, while instant claims recite PEG as a carrier, Holt teaches the same as an anesthetic agent, which provides the same benefit as that intended in the instant invention i.e., the PEG of Holt also reduces the discomfort (pruritis, neuropathic pain etc.) caused by capsaicin. Holt, even though teaches PEG, differs from the instant claims in that the reference does not teach washing capsaicin with a composition containing PEG, to solubilize capsaicin. Holt teaches applying the composition as a patch, but does not teach the claimed features of

Art Unit: 1615

the transdermal patch. However, it is implicit that a capsaicin containing transdermal patch of Holt includes a reservoir of capsaicin and carrier as well as a second anesthetic agent for its proper release of the active agents and the carrier through the skin.

Wholehealthmd describes a capsaicin product by the names Axsain and Zostrix, and teaches that capsaicin is prescribed for topical application to relieve the neurological pain, mild to moderate arthritis etc. The data sheet also describes that the common side effects of capsaicin include burning, stinging sensation and suggests washing hands thoroughly after applying the capsaicin containing cream so as to prevent as well as reduce the burning and stinging sensation caused by capsaicin. Therefore, it would have been obvious for one of an ordinary skill in the art at the time of the instant invention to dilute the amount of capsaicin applied on the skin of a person in need of capsaicin treatment, by washing it with a composition containing capsaicin solubilizer or another anesthetic agent, because Wholehealthmd suggests diluting the amount of capsaicin on the skin, because capsaicin is known to cause burning and stinging sensation while simultaneously providing relief from itching due to poison ivy, arthritis etc (Holt). Accordingly, a skilled artisan would have been motivated to prepare a kit containing capsaicin as an active ingredient, a carrier, and a second anesthetic agent such as PEG of Holt, with the required instructions to use the kit for providing capsaicin treatment. Further, it would have been obvious for a skilled artisan to use an appropriate amount of PEG (of Holt) to effectively dilute (or neutralize) the amount of capsaicin on the skin. Further, absent criticality, choosing an appropriate thickener and pH of the

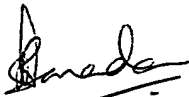
Art Unit: 1615

composition so as to formulate the composition in the desired form i.e., a cream or lotion or a gel would have been within the scope of a skilled artisan.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lakshmi S. Channavajjala whose telephone number is 571-272-0591. The examiner can normally be reached on 9.00 AM -6.30 PM

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on 571-272-0602. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Lakshmi S Channavajjala
Examiner
Art Unit 1615

May 31, 2005